

### Remarks

After entry of this amendment, claims 1, 3-22, 24 and 25-27 are pending in the present application. Claim 1 is currently amended by inclusion of multiparticulate form having "coated particles". No new matter was added by this amendment since original claim 18 provided specific support. Claim 2 is amended to correct claim dependency from canceled Claim 2 to Claim 1. Newly presented claims 26 and 27 set forth 5% to 50%; and 10% to 50% by weight of coating respectively. Support is found at page 8 line 9-13 and elsewhere.

### **CLAIM REJECTIONS UNDER 35 U.S.C. § 103(A)**

The Examiner rejects claims 1, 3-22, 24 -25 under 35 U.S.C. § 103(a) as allegedly unpatentable over two combinations: 1) Jans in combination with U.S. Patent No. 5,607,697 to Alkire et al ("Jans-Alkire"), and 2) Jans in combination with U.S. Patent No. 5,354,556 to Sparks ("Jans-Sparks"). This rejection is respectfully traversed.

The present application is directed to palatable, chewable controlled release compositions that include a pharmaceutically active agent in controlled release multiparticulate form and a palatability improving agent.

In contrast, Jans discloses palatable compositions, without teaching controlled release compositions or multiparticulate forms with coated particles.

Applicants renew the contention raised in the earlier filed response, without repeating it, that the amended claims are not *prima facie* obvious in view of Jans-Alkire or Jans-Sparks.

The Examiner accurately notes that Jans does not teach controlled release. The Examiner suggests that granulating the active agent with a binder will achieve the same result as we desire. This is not true. Jans uses them as binders in very small amounts (up to 4% by weight). This small amount of polymer is insufficient to produce sustained release or delayed release because it is not sufficient to coat the granules (it is only enough to hold drug particles together). The small amounts of the binders of Jans do not make it a controlled release dosage form.

Claims 18 through 21 set forth one embodiment, wherein "said coating being present in an amount of about 5% to 100% by weight". In order to have controlled release using multiparticulates, a higher coating level of a polymer is needed. For example, in the specification, in particular, Example 13, 27% ethylcellulose or 15% Eudragit S100 is used; in Example 15, 15, 25, and 45% coating is used; in Example 19, 10 to 50% coating is used. This provides support for claim 18.

In general, the simple process of granulation of Jans is not an efficient way of coating. Process Claims 24 and 25 sets forth desired methods for accomplishing coverage of multiparticulates. In the specification the examples use fluid bed coating and coating by spray drying to create a coating that surrounds the drug particles to effect controlled release properties.

Alkire provides little practical guidance for one of ordinary skill to combine with Jans. Alkire describes a dosage form that is an orally disintegrating tablet while ours is a controlled release palatable formulation. Once again, the principles of formulating an orally disintegrable tablet, where fast dissolution and absorption of the drug are objectives are quite distinct and potentially in opposition to the objectives of controlled release dosage form where slow dissolution and absorption of the drug is desirable.

Because Alkire's tablet is orally disintegrable (he requires tablets to disintegrate in less than 10 min and desirably less than 1 min and most preferably as fast as possible- in a few seconds), he requires that the tablet must include disintegrating agents- both effervescent or non-effervescent, or a combination of them (acids and carbonate or bicarbonate). We have no such ingredient in our formulation.

Sparks relates specifically to micro-particles in the form of a micromatrix of an active ingredient uniformly distributed in at least one non-toxic polymer. Thus, Sparks is not a coating concept, but rather a matrix concept which would provide no guidance to combine with Jans.

Given the amendment to claim 1 setting forth the coated particles (emphasis added) feature of the multiparticulate form, a skilled worker would have scant motivation to combine Jans with either Alkire or Sparks. Jans, Alkire, and Sparks all relate to different types of compositions: Jans to palatable chewable tablets, but not controlled release or multiparticulate form; and Alkire to effervescent, microparticle delivery systems; and Sparks to specialized micro-particles in the form of a micromatrix.

Given these many differences in approaches and objectives, a skilled worker would not be motivated to combine these references, nor to expect success from such a combination.

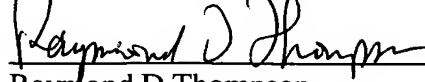
Applicants believe that further and favorable action in the form of a Notice of Allowance Issue is next in order, and such action is earnestly solicited.

A petition for a three month extension of time is included herewith; as such, the Commissioner is hereby authorized to charge the two month extension of time fee, and any other fees that may be required, or credit any overpayment, to Deposit Account No. 16-1445.

A prompt and favorable response is earnestly solicited.

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Respectfully submitted,



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